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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,591	07/25/2003	Andrew Clark	PAT053229-US-CNT02	2973

1095 7590 07/13/2010

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 101/2
EAST HANOVER, NJ 07936-1080

EXAMINER	
DOUGLAS, STEVEN O	

ART UNIT	PAPER NUMBER
3771	

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07/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10627591	7/25/03	CLARK ET AL.	PAT053229-US-CNT02

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EXAMINER
/Steven O.. Douglas/

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/Steven O. Douglas/
Primary Examiner
Art Unit: 3771

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/627,591
Filing Date: July 25, 2003
Appellant(s): CLARK ET AL.

Guy V. Tucker
For Appellant

EXAMINER'S ANSWER

This Examiner's Answer is in response to the Remand from the Board of Appeals dated 6/3/10 and replaces the Examiner's Answer of 8/14/09.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed is correct.

NEW GROUND(S) OF REJECTION

Claims 33-37 are rejected under 35 USC § 112, ¶ 1, as not being enabled for the scope of the claim. The claims are drafted in a means plus function format and recites/recite only a single means. The claim(s) is/are drawn to only a single element instead of a combination

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,735,263	**Rubsamen et al.**	**4-1998**

(9) Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23,24,26, and 28-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Rubsamen et al. US 5,735,263.

Regarding claims 23, 29, 28, 31-36, and 38-40, Rubsamen discloses a device (see the device of figs.1 and 10) for increasing the bioavailability of an aerosolized active agent, said device comprising a flow restrictor (9,22,37). Rubsamen in column 5, lines 50-55, column 13,

lines 5-10, 25-30, and 52-57, column 23, lines 34-55 discloses that a microprocessor controls and monitors the inspiratory flow of an aerosolized active agent formulation to a human patient (though the valve in the case of fig.1 and though the opening of the mouthpiece in the case of fig.10) at a rate of 0.1 to 2 liters per second ~ 6 to 12 liters per minute, which meets claimed flow rate of "less than 17 liters per minute" and "10 liters per minutes". Rubsamen further discloses wherein the device is adapted to aerosolize the active agent formulation and wherein the active agent formulation is (i) a powder, (ii) a solution, suspension, or slurry that may be nebulized, or (iii) suspended or dissolved in a propellant (see col.14, lines 64-67, and col.15, lines 1-6). Rubsamen further discloses the active agent formulation is a powder (see col.14, lines 64-67, and col.15, lines 1-6) and the device is adapted to aerosolize the active agent formulation (see col.29, lines 26 and 27) using compressed air (see col.31, lines 15-20). Rubsamen further specifically discloses the device is adapted to be used with an active agent selected from the group consisting of insulin (see col.22, lines 49 and 50).

Regarding claim 26, Rubsamen discloses the flow restrictor is a valve (fig.1, 9) and microprocessor (22,27) controlling the inspiratory flow rate though the valve would provide for adjustment of the valve so that it decreasing resistance with increasing flow rate in order to provide an inspiratory flow rate of 6-12 liters per minutes.

Regarding claims 30,37, 41, 46, and 52, Rubsamen in figure 10 discloses the active agent formulation is contained in a blister (56) and the device is adapted to receive the blister.

Regarding claims 24, 42-45, Rubsamen discloses the claimed invention as applied for claims 23, 29, 28, 31-36, and 38-40. Notice, opening through the mouthpiece in figure 10 and flow passage blocked by the valve in figure 1 is considered orifice of claims 24 and 42.

Regarding claims 47 and 48, Rubsamen discloses a device (see fig.1 and 10) for delivering an aerosolized active agent to the lungs of a human patient, said device comprising a chamber (3,55) in flow communication with a mouthpiece (12,52), means for aerosolizing the active agent (actuator/switch (see col.17, lines 15-17) releasing active agent into a flow path (8/54) would allow aerosolization of the agent in the air contained into the flow path; and patient's inhalation force can further assist in aerosolization of the active agent), and means for limiting an inspiratory flow rate (9,22,37). Rubsamen discloses flow rate of less than 17 liters per minute and 10 liters per minute or less as applied for claim 23. Rubsamen further discloses whereby an aerosolized active agent formulation in the chamber may be delivered to the human patient, the active agent formulation being (i) powder, (ii) a solution suspension, or slurry than may be nebulized, or (iii) suspended or dissolved in a propellant (see col.14, lines 64-67, and col.15, lines 1-6).

Regarding claim 49, Rubsamen discloses the device is adapted to deliver an aerosolized insulin formulation to the lungs Rubsamen further specifically discloses the device is adapted to be used with an active agent selected from the group consisting of insulin (see col.22, lines 49 and 50).

Regarding claim 49, Rubsamen discloses the device is adapted to deliver an aerosolized insulin formulation to the lungs (see col.22, lines 49 and 50).

Regarding claim 50, Rubsamen discloses the device further comprising means for aerosolizing the active agent (see compressed air in col.31, lines 15-20).

Regarding claim 51, Rubsamen discloses the active agent formulation is a powder (see col.14, lines 64-67, and col.15, lines 1-6) and the device is adapted to aerosolize the active agent formulation (see col.29, lines 26 and 27).

NEW GROUND(S) OF REJECTION

Claims 33-37 are rejected under 35 USC § 112, ¶ 1, as not being enabled for the scope of the claim. The claims are drafted in a means plus function format and recites/recite only a single means: A device for delivering an aerosolized active agent to the lungs of a human patient, wherein said device is adapted to deliver an aerosolized active agent formulation at an inspiratory flow rate limited to a rate less than 17 liters per minute, wherein the device is adapted to aerosolize the active agent formulation and wherein the active agent formulation is (i) a powder, (ii) a solution, suspension, or slurry that may be nebulized, or (iii) suspended or dissolved in a propellant.

In regard to claim 33, claim 33 is defined in terms of function and sets forth no new structure in the claim, necessarily invoking 35 U.S.C. 112, 6th, paragraph.

A mere recital of a multitude of elements or steps in a claim is not determinative of the invention it defines. In claim 33, the invention defined is what follows the word "wherein" (line 2). Appellant's denomination of every noun in the claim as a separate element ignores the fact that these words function as mere description of the single claimed means. Therefore, the claim is drafted in means plus function format and it is drawn to a single element. See MPEP 2164.08(a).

In regard to claims 34-37, these claims are rejection based on their dependence from claim 33.

Thus, every claim listed above is a single means claim.

A single means claim covers every conceivable means for achieving the stated result while the specification discloses at most only those means known to the inventor. *See O'Reilly v. Morse,* 56 U.S. 62, 112, 14, L. Ed. 601 (1853). The U.S. Court of Appeals for the Federal

Circuit stated that such a claim is properly rejected based on the first of paragraph of 35 USC § 112, ¶ 1. *In re Hyatt,* 708 F .2d 712, 714-715 (Fed. Cir. 1983).

(10) Response to Argument

In regard to Appellant's argument that Rubsamen et al. fails to anticipate independent claim 23 because Rubsamen et al. does not in any way limit the inspiratory flow of an aerosolized active agent to a rate less than 17 liters per minute by way of a "flow restrictor" (see Appellant's brief on page 5, line 9 through page 7, line 22), Examiner disagrees. As pointed out in the rejection, the Rubsamen et al. device operates at a flow rate well within the claimed range (i.e. Examiner acknowledges that the Rubsamen et al. device operates at flow rates exceeding the claimed range, but Examiner reiterates that the device is still capable of operating at flow rates within the claimed range.) and that it is the operation of the Rubsamen et al. solenoid valve that restricts the flow rate within the claimed rate. Furthermore, giving the term "restriction" or "restrictor" its broadest most reasonable interpretation, a conventional valve (i.e. a solenoid-type or not) includes at least one of an orifice, opening or passage that includes a designed flow rate that is further actuated (i.e. restricted) by the associated valve element.

In regard to Appellant's argument that Rubsamen et al. fails to anticipate independent claim 33 because Rubsamen et al. does not in any way limit the inspiratory flow of an aerosolized active agent to a rate less than 17 liters per minute by way of a "device that limits

inspiratory flow " (see Appellant's brief on page 7, line 23 through page 8, line 6), Examiner disagrees. As pointed out in the rejection, the Rubsamen et al. device operates at a flow rate well within the claimed range (i.e. Examiner acknowledges that the Rubsamen et al. device operates at flow rates exceeding the claimed range, but Examiner reiterates that the device is still capable of operating at flow rates within the claimed range.) and that it is the operation of the Rubsamen et al. solenoid valve restricts the flow rate within the claimed rate. Furthermore, giving the term "a device that limits inspiratory flow" its broadest most reasonable interpretation, a conventional valve (i.e. a solenoid-type or not) includes at least one of an orifice, opening or passage that includes a designed flow rate that is further actuated (i.e. restricted or limited) by the associated valve element.

In regard to Appellant's argument that Rubsamen et al. fails to anticipate independent claim 38 because Rubsamen et al. does not in any way limit the inspiratory flow of an aerosolized active agent to a rate less than 17 liters per minute by way of a "flow restrictor" (see Appellant's brief on page 8, lines 7-16), Examiner disagrees. As pointed out in the rejection, the Rubsamen et al. device operates at a flow rate well within the claimed range (i.e. Examiner acknowledges that the Rubsamen et al. device operates at flow rates exceeding the claimed range, but Examiner reiterates that the device is still capable of operating at flow rates within the claimed range.) and that it is the operation of the Rubsamen et al. solenoid valve restricts the flow rate within the claimed rate. Furthermore, giving the term "a flow restrictor" its broadest most reasonable interpretation, a conventional valve (i.e. a solenoid-type or not) includes at least

one of an orifice, opening or passage that includes a designed flow rate that is further actuated (i.e. restricted) by the associated valve element.

In regard to Appellant's argument that Rubsamen et al. fails to anticipate independent claim 42 because Rubsamen et al. does not in any way limit the inspiratory flow of an aerosolized active agent to a rate less than 17 liters per minute by way of "one or more orifices" (see Appellant's brief on page 8, line 17 through page 9, line 4), Examiner disagrees. As pointed out in the rejection, the Rubsamen et al. device operates at a flow rate well within the claimed range (i.e. Examiner acknowledges that the Rubsamen et al. device operates at flow rates exceeding the claimed range, but Examiner reiterates that the device is still capable of operating at flow rates within the claimed range.) and that it is the operation of the Rubsamen et al. solenoid valve restricts the flow rate within the claimed rate. Furthermore, giving the term "a flow restrictor" its broadest most reasonable interpretation, a conventional valve (i.e. a solenoid-type or not) includes *at least one of an orifice*, opening or passage that includes a designed flow rate that is further actuated (i.e. restricted) by the associated valve element.

In regard to Appellant's argument that Rubsamen et al. fails to anticipate independent claim 47 because Rubsamen et al. does not in any way limit the inspiratory flow of an aerosolized active agent to a rate less than 17 liters per minute by way of a "means for limiting an inspiratory flow rate" (see Appellant's brief on page 9, lines 5-15), Examiner disagrees. As pointed out in the rejection, the Rubsamen et al. device operates at a flow rate well within the claimed range (i.e. Examiner acknowledges that the Rubsamen et al. device operates at flow

rates exceeding the claimed range, but Examiner reiterates that the device is still capable of operating at flow rates within the claimed range.) and that it is the operation of the Rubsamen et al. solenoid valve restricts the flow rate within the claimed rate. Furthermore, giving the term "a means for limiting an inspiratory flow rate" its broadest most reasonable interpretation, a conventional valve (i.e. a solenoid-type or not) includes at least one of an orifice, opening or passage that includes a designed flow rate that is further actuated (i.e. restricted) by the associated valve element.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

The following ground(s) of rejection are applicable to the appealed claims:

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/Steven O. Douglas/
Primary Examiner
Art Unit 3771

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/DONALD T HAJEC/
Director, Technology Center 3700

Conferees:

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

/Janet C. Baxter/
TC 3700 TQAS